

Collected Scientific Research Relating to the Use of Osteopathy with Psychological conditions (including anxiety and depression) and associated physiology

Important:

1) Osteopathy involves helping people's own self-healing abilities to work better, rather than focussing primarily on particular conditions.

2) Each person is different, and osteopathy treats them differently.

Therefore people respond to osteopathic treatment in different ways. Treatments that work for one person cannot be guaranteed to work for another person in the same way. The fact that there is scientific research supporting a treatment in a group of people does not mean that it will always work in the same way (which is probably true of all research).

A number of things make research into osteopathy challenging. These include the two aspects of osteopathy mentioned above, and also the lack of major commercial interests to provide funding in expectation of financial returns. At the same time, there is an emerging body of research demonstrating the usefulness of osteopathic treatment.

More research is being done all of the time. I am not aware of any research which shows that osteopathic treatment, delivered by a qualified osteopath, is ineffective in relation to this area. If you are aware of any studies that show that, please bring them to my attention.

Please note: there is room for debate about the classifications used for these studies. Please let John Smartt know if you believe that any of these classifications are incorrect.

Some of the studies that are listed here deal primarily with states of physical pain and dysfunction, and also mention emotional benefits of treatment.

Other studies deal specifically with the emotional benefits of treatment, while others measure the physiological and neuro-endocrine responses. (For those not medically trained, an increased "vagal" or "parasympathetic" response, or a decreased "sympathetic response", indicated that the subject has a lowered physiological response to perceived stresses in the environment. He or she is more relaxed.

These studies are from peer-reviewed journals

Number
of studies:
33

Clinically and statistically significant results

Number
of studies:
31

Systematic reviews

Number of studies: 4

Saracutu M, Davies H, Edwards DJ 2018 **The effects of osteopathic treatment on psychosocial factors in people with persistent pain: A systematic review** The effects of osteopathic treatment on psychosocial factors in people with persistent pain: A systematic review March, Volume 27, Pages 23–33 [https://www.journalofosteopathicmedicine.com/article/S1746-0689\(16\)30116-X/abstract](https://www.journalofosteopathicmedicine.com/article/S1746-0689(16)30116-X/abstract)

"Persistent pain is considered a complex biopsychosocial phenomenon whose understanding and management is yet to be improved. More research is needed to determine the common paths that lead to developing persistent pain, to identify the populations most at risk and to develop and evaluate interventions. The last decades have seen a shift in pain management, from the biomedical model to a biopsychosocial model. There is also a significant body of evidence emphasizing the effects of osteopathy in persistent pain management. Given the relevance of psychosocial factors in aetiology and maintenance of pain, it is essential to investigate whether osteopathy has an influence on depression, anxiety, fear avoidance or pain catastrophizing. This review will identify and synthesize relevant primary research focused on the effects of osteopathic interventions on psychosocial factors in patients living with different pain conditions."

"A total of 16 RCTs were selected. Two out of five reported significant differences in depression; in regards to anxiety, all the four trials found significant effects; two out of three trials reported a significant reduction in fear avoidance while six out of seven trials found a significant enhancement of health status and three out of four found an increase in quality of life. The findings of this review are encouraging; suggesting that osteopathic treatment may have some effects on anxiety, fear avoidance, quality of life and general health status in populations living with persistent pain."

Luis B, Borgesa A, Luiz G, Hugo B, Netoab P 2018 **Effects of spinal manipulation and myofascial techniques on heart rate variability: A systematic review** Journal of Bodywork and Movement Therapies Volume 22, Issue 1, January , Pages 203-208 <https://www.ncbi.nlm.nih.gov/pubmed/29332747>

"Background: The analysis of heart rate variability is important to the investigation of stimuli from the autonomic nervous system. Osteopathy is a form of treatment that can influence this system in healthy individuals as well as those with a disorder or disease.

Objectives: The aim of the present study was to perform a systematic review of the literature regarding the effect of spinal manipulation and myofascial techniques on heart rate variability.

Methods: Searches were performed of the Pubmed, Scielo, Lilacs, PEDro, Ibesco, Cochrane and Scopus databases for relevant studies. The PEDro scale was used to assess the methodological quality of each study selected.

Results: A total of 505 articles were retrieved during the initial search. After an analysis of the

abstracts, nine studies were selected for the present review.

Conclusion: Based on the findings, osteopathy exerts an influence on the autonomic nervous system depending on the stimulation site and type. A greater parasympathetic response was found when stimulation was performed in the cervical and lumbar regions, whereas a greater sympathetic response was found when stimulation was performed in the thoracic region."

Williams NH, Hendry M, Lewis R, Russell I, Westmoreland A, Wilkinson C. 2007 **Psychological response in spinal manipulation (PRISM): a systematic review of psychological outcomes in randomised controlled trials**. *Complementary Therapies in Medicine* Dec;15(4):271-83 <http://dx.doi.org/10.1016/j.ctim.2007.01.008>

"One hundred and twenty nine RCTs of spinal manipulation were identified; 12 had adequately reported psychological outcomes. Six trials with a verbal intervention comparator were combined in a meta-analysis, and found a mean benefit from spinal manipulation equivalent to 0.34 of the population standard deviation (S.D.) [95% confidence interval (CI) 0.23–0.45] at 1–5 months; 0.27 of the S.D. [95% CI 0.14–0.40] at 6–12 months. Eight trials with a physical treatment comparator were combined in a meta-analysis and found a mean benefit of 0.13 of the S.D. [95% CI 0.01–0.24] in favour of manipulation at 1–5 months; 0.11 of the S.D. [95% CI –0.02 to 0.25] at 6–12 months."

"There was some evidence that spinal manipulation improved psychological outcomes compared with verbal interventions."

Pepino VC, Ribeiro JD, Ribeiro MA, de Noronha M, Mezzacappa MA, Schivinski CI. 2013 **Manual therapy for childhood respiratory disease: a systematic review**. *Journal of Manipulative and Physiological Therapeutics* Jan;36(1):57-65 <http://www.ncbi.nlm.nih.gov/pubmed/23380215>

"Of the 8 studies included in the present review, 5 consisted of asthmatic children and the others of children with the following conditions: cystic fibrosis, bronchiolitis, recurrent respiratory infections, among others. Only 2 studies did not identify positive results with the use of manual therapy. The other 6 studies found some benefit, specifically in spirometric parameters, immunologic tests, anxiety questionnaire, or level of salivary cortisol."

"The use of manual techniques on children with respiratory diseases seems to be beneficial. Chiropractic, osteopathic medicine, and massage are the most common interventions. The lack of standardized procedures and limited variety of methods used evidenced the need for more studies on the subject."

Martí-Salvador M, Hidalgo-Moreno L, Doménech-Fernández J, Lisón JF, Arguisuelas MD. 2018 **Osteopathic manipulative treatment including specific diaphragm techniques improves pain and disability in chronic non-specific low back pain: a randomized trial.** Arch Phys Med Rehabil May 19 <https://www.ncbi.nlm.nih.gov/pubmed/29787734>

"OBJECTIVE:

To investigate the effects of an osteopathic manipulative treatment (OMT) which includes a diaphragm intervention compared to the same OMT with a sham-diaphragm intervention in chronic non-specific low back pain (NS-CLBP).

DESIGN:

Parallel group randomized controlled trial SETTING: private and institutional health centers.

PARTICIPANTS:

Sixty-six subjects (18-60 yrs.) with a diagnosis of NS-CLBP lasting at least 3 months.

INTERVENTIONS:

Participants were randomized to receive either an OMT protocol including specific diaphragm techniques (n=33) or the same OMT protocol with a sham-diaphragm intervention (n=33), conducted in five sessions provided during 4 weeks.

MAIN OUTCOME MEASURE:

The primary outcomes were pain [evaluated with the Short-Form McGill Pain Questionnaire (SF-MPQ) and the Visual Analogue Scale (VAS)] and disability [assessed with the Roland Morris Questionnaire (RMQ) and the Oswestry Disability Index (ODI)]. Secondary outcomes were fear-avoidance beliefs, level of anxiety and depression, and pain catastrophization. All outcome measures were evaluated at baseline, at week 4, and at week 12.

RESULTS:

A statistically significant reduction was observed in the experimental group compared to the sham group, in all variables assessed at week 4 and at week 12 [SF-MPQ (MD -6.2;95%CI: -8.6 to -3.8); VAS (MD -2.7;95%CI: -3.6 to -1.8); RMQ (MD -3.8;95%CI: -5.4 to -2.2); ODI (MD -10.6;95%CI: -14.9 to 6.3)]. Moreover, improvements in pain and disability were clinically relevant.

CONCLUSION:

An OMT protocol that includes diaphragm techniques produces significant and clinically relevant improvements in pain and disability in patients with NS-CLBP compared to the same OMT protocol using sham diaphragm-techniques.

Carnes D, Marsa T, Plunkett L, Nankeeb N, Abbey H 2017 **A mixed methods evaluation of a third wave cognitive behavioural therapy and osteopathic treatment programme for chronic pain in primary care (OsteoMAP)** International Journal of Osteopathic Medicine Volume 24, June 2017, Pages 12-17 <http://www.sciencedirect.com/science/article/pii/S1746068916300839>

"This evaluation included a non-randomised before-and-after patient reported outcomes study with an embedded fidelity evaluation. Patients were seen for 1 h per week for six weeks. They received a questionnaire prior to receiving treatment and six months later. A purposive sample of patients were interviewed and clinical sessions were observed to evaluate competence and adherence to the intervention manual.

Results

208 patients were enrolled and 86% attended 3 or more OsteoMAP sessions. 82 students were trained to deliver the intervention under supervision. They were >90% adherent to the manual in 8 of the 12 domains measured. At baseline (n = 147), 69% of patients were female, 64% white and 77% reported pain for more than one year. At 6 months (matched pairs n = 63), there were clinically important changes of 58% in a composite score for pain, function, mood and coping (Bournemouth Questionnaire) and significantly higher psychological flexibility scores (difference in means 6.98 (95% CI 4.2,9.8)) (Acceptance and Action Questionnaire). No statistically significant change was seen in mindfulness (Freiburg Mindfulness Inventory), 30% of patients reported temporary symptom increases during the course but 95% were satisfied or very

satisfied with their overall experience and outcomes.

Conclusions

OsteoMAP was feasible, well received with some beneficial effects. Integrating psychological and osteopathic care shows promise and further research is warranted to assess effectiveness."

Fornari M, Carnevali L, Sgoifo A 2017 **Single Osteopathic Manipulative Therapy Session Dampens Acute Autonomic and Neuroendocrine Responses to Mental Stress in Healthy Male Participants**. *J Am Osteopath Assoc Sep 1;117(9):559-567* <http://jaoa.org/article.aspx?articleid=2652668>

"Context: The efficacy of osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) is supported by observational data and patient feedback, but there is still a need for objective, quantitative biomarkers that allow measurement of the underlying mechanisms. No study exploring the protective potential of OMTh for mental stress has been published, to the authors' knowledge.

Objectives: To explore the modulating effect of OMTh on autonomic neural regulation of the heart and verify its ability to influence the activity of the hypothalamic-pituitary-adrenocortical axis.

Methods: Healthy young adult men who had never received OMTh were exposed to either a brief protocol using craniosacral techniques or sham therapy (control) involving the same anatomical areas. A laboratory stress episode consisting of a 5-minute arithmetic task participants were required to perform in front of a committee preceded the therapy sessions. Continuous electrocardiograph recordings were done before, during, and after the stress episode. Heart rate and frequency-domain parameters of heart rate variability (specifically, high-frequency component power in normalized units and the ratio of low-frequency to high-frequency power) were measured to quantify the activity of the parasympathetic nervous system and the state of sympathovagal balance at the level of the heart, respectively. Saliva samples were also collected at points throughout the study to determine cortisol levels.

Results: Osteopathic manipulative therapy reduced the overall chronotropic effect of the stressor ($t=-2.9$, $P<.05$) and counteracted the vagal withdrawal and the shift of autonomic balance toward sympathetic prevalence ($t=-2.8$, $P<.05$) that were observed in control participants. Moreover, OMTh participants had a much lower overall cortisol level during the mental stressor compared with control participants ($t=-2.3$, $P<.05$). Participants in the OMTh group did not show the statistically significant reduction in the amplitude of the cortisol awakening response observed in their control counterparts after the stress episode (control: $t=2.7$, $P<.05$; OMT: $P=.83$).

Conclusion: The application of a single OMTh session to healthy participants induced a faster recovery of heart rate and sympathovagal balance after an acute mental stressor by substantially dampening parasympathetic withdrawal and sympathetic prevalence. The OMTh session also prevented the typical increase in cortisol levels observed immediately after a brief mental challenge."

Henderson AT, Fisher JF, Blair J, Shea C, Li TS, Bridges KG. 2010 **Effects of rib raising on the autonomic nervous system: a pilot study using noninvasive biomarkers**. *J Am Osteopath Assoc Jun;110(6):324-30* <http://www.ncbi.nlm.nih.gov/pubmed/20606239>

"Changes in salivary biomarkers after rib raising were investigated using a pretest-posttest, placebo-controlled design. Healthy adult participants were recruited and randomly assigned to rib raising or placebo (light touch) groups. All participants provided baseline saliva samples and samples immediately and 10 minutes after receiving the rib raising or placebo procedure. Salivary flow rate, alpha-amylase activity, and cortisol levels were measured for each sample."

"Twenty-three participants were recruited, of whom 14 completed the study (7 in each group).

Subjects who received rib raising had a statistically significant decrease in alpha-amylase activity both immediately after ($P=.014$) and 10 minutes after ($P=.008$) the procedure. A statistically significant change in alpha-amylase activity was not seen in the placebo group at either time point. Changes in salivary cortisol levels and flow rate were not statistically significant in either group."

"The results of the present pilot study suggest that SNS activity may decrease immediately after rib raising, but the hypothalamic-pituitary-adrenal axis and parasympathetic activity are not

altered by this technique. Salivary alpha-amylase may be a useful biomarker for investigating manipulative treatments targeting the SNS. Additional studies with a greater number of subjects are needed to expand on these results."

Kim SJ, Kwon OY, Yi CH. 2009 **Effects of manual lymph drainage on cardiac autonomic tone in healthy subjects**. *Int J Neurosci* 119(8):1105-17. <http://www.ncbi.nlm.nih.gov/pubmed/19922342>

"This study was designed to investigate the effects of manual lymph drainage on the cardiac autonomic tone. Thirty-two healthy male subjects were randomly assigned to manual lymph drainage (MLD) (experimental) and rest (control) groups. Electrocardiogram (ECG) parameters were recorded with bipolar electrocardiography using standard limb lead positions. The pressure-pain threshold (PPT) was quantitatively measured using an algometer. Heart rate variability differed significantly between the experimental and control groups ($p < 0.05$), but the PPT in the upper trapezius muscle did not ($p > 0.05$). These findings indicate that the application of MLD was effective in reducing the activity of the sympathetic nervous system."

Stringer J, Swindell R, Dennis M 2008 **Massage in patients undergoing intensive chemotherapy reduces serum cortisol and prolactin**. *Psychooncology* Oct;17(10):1024-31 <https://www.ncbi.nlm.nih.gov/pubmed/18300336>

OBJECTIVE:

The objective is to identify whether single 20 min massage sessions were safe and effective in reducing stress levels of isolated haematological oncology patients.

DESIGN:

Based on a randomised controlled trial, 39 patients were randomised to aromatherapy, massage or rest (control) arm.

MEASURES:

The measures were serum cortisol and prolactin levels, quality of life (EORTC QLQ-C30) and semi-structured interviews. Primary outcome measure was the fall in serum cortisol levels.

RESULTS:

A significant difference was seen between arms in cortisol ($P=0.002$) and prolactin ($p=0.031$) levels from baseline to 30 min post-session. Aromatherapy and massage arms showed a significantly greater drop in cortisol than the rest arm. Only the massage arm had a significantly greater reduction in prolactin than the rest arm. The EORTC QLQ-C30 showed a significant reduction in 'need for rest' for patients in both experimental arms compared with the control arm, whereas the semi-structured interviews identified a universal feeling of relaxation in patients in the experimental arms.

CONCLUSION:

This pilot study demonstrated that in isolated haematological oncology patients, a significant reduction in cortisol could be safely achieved through massage, with associated improvement in psychological well-being. The implications are discussed."

Duncan B, Barton L, Edmonds D, Blashill BM 2004 **Parental perceptions of the therapeutic effect from osteopathic manipulation or acupuncture in children with spastic cerebral palsy**. *Clin Pediatr (Phila)* <https://www.ncbi.nlm.nih.gov/pubmed/15118778>

"Fifty children were involved in a randomized, controlled trial to evaluate the effectiveness of either osteopathic manipulation or acupuncture as a 6-month therapeutic adjunct for children with spastic cerebral palsy. Exit interviews were used to obtain parental perceptions and form the basis of this report. Only 2 of 17 parents reported positive gains while their child was in a wait-list control period but all 17 reported gains while in the treatment phase of the study. Ninety-six percent (48 of 50) of the parents reported some improvement while their child was receiving treatments but the gains varied from child to child. The most frequent gains were seen in improvement in the use of arms or legs (61% and 68%) and more restful sleep (39% and 68%) in the osteopathic and the acupuncture groups, respectively. Improvement in mood and improved bowel function were also very common benefits noted by the parents in both groups."

Hernandez-Reif M, Ironson G, Field T, Hurley J, Katz G, Diego M, Weiss S, Fletcher MA, Schanberg S, Kuhn C, Burman I. 2004 **Breast cancer patients have improved immune and neuroendocrine functions following massage therapy.** *J Psychosom Res* Jul;57(1):45-52 <https://www.ncbi.nlm.nih.gov/pubmed/15256294>

"OBJECTIVES:

Women with breast cancer are at risk for elevated depression, anxiety, and decreased natural killer (NK) cell number. Stress has been linked to increased tumor development by decreasing NK cell activity. The objectives of this study included examining massage therapy for women with breast cancer for (1) improving mood and biological measures associated with mood enhancement (serotonin, dopamine), (2) reducing stress and stress hormone levels, and (3) boosting immune measures.

METHODS:

Thirty-four women (M age=53) diagnosed with Stage 1 or 2 breast cancer were randomly assigned postsurgery to a massage therapy group (to receive 30-min massages three times per week for 5 weeks) or a control group. The massage consisted of stroking, squeezing, and stretching techniques to the head, arms, legs/feet, and back. On the first and last day of the study, the women were assessed on (1) immediate effects measures of anxiety, depressed mood, and vigor and (2) longer term effects on depression, anxiety and hostility, functioning, body image, and avoidant versus intrusive coping style, in addition to urinary catecholamines (norepinephrine, epinephrine, and dopamine) and serotonin levels. A subset of 27 women (n=15 massage) had blood drawn to assay immune measures.

RESULTS:

The immediate massage therapy effects included reduced anxiety, depressed mood, and anger. The longer term massage effects included reduced depression and hostility and increased urinary dopamine, serotonin values, NK cell number, and lymphocytes.

CONCLUSIONS:

Women with Stage 1 and 2 breast cancer may benefit from thrice-weekly massage therapy for reducing depressed mood, anxiety, and anger and for enhancing dopamine, serotonin, and NK cell number and lymphocytes."

Joan G. Turner DSN RN CIC1, Ann J. Clark PhD RN2, Dorothy K. Gauthier PhD RN3, Monica Williams BA MA4 1998 **The effect of therapeutic touch on pain and anxiety in burn patients** *Journal of Advanced Nursing* Jul;28(1):10-20 <https://www.ncbi.nlm.nih.gov/pubmed/9687125>

The purpose of this single-blinded randomized clinical trial was to determine whether therapeutic touch (TT) versus sham TT could produce greater pain relief as an adjunct to narcotic analgesia, a greater reduction in anxiety, and alterations in plasma T-lymphocyte concentrations among burn patients. Therapeutic touch is an intervention in which human energies are therapeutically manipulated, a practice conceptually supported by Rogers' (1970) theory of unitary human beings. Data were collected at a university burn centre in the south-eastern United States. The subjects were 99 men and women between the ages of 15 and 68 hospitalized for severe burns, and they received either TT or sham TT once a day for 5 days. Baseline data were collected on day 1, data were collected before and after treatment on day 3, and post-intervention data were collected on day 6. Instruments included the McGill Pain Questionnaire, Visual Analogue Scales for Pain, Anxiety and Satisfaction with Therapy, and an Effectiveness of Therapy Form. Blood was drawn on days 1 and 6 for lymphocyte subset analysis. Medication usage for pain in mean morphine equivalents, and mean doses per day of sleep, anxiety and antidepressant medications were recorded. Subjects who received TT reported significantly greater reduction in pain on the McGill Pain Questionnaire Pain Rating Index and Number of Words Chosen and greater reduction in anxiety on the Visual Analogue Scale for Anxiety than did those who received sham TT. Lymphocyte subset analyses on blood from 11 subjects showed a decreasing total CD8+lymphocyte concentration for the TT group. There was no statistically significant difference between groups on medication usage.

Saggio G, Docimo S, Pilc J, Norton J, Gilliar W. 2011 **Impact of osteopathic manipulative treatment on secretory immunoglobulin a levels in a stressed population.** *J Am Osteopath Assoc* Mar;111(3):143-7 <http://www.ncbi.nlm.nih.gov/pubmed/21464262>

"High levels of human secretory immunoglobulin A (sIgA) have been shown to decrease the incidence of acquiring upper respiratory tract infections. Osteopathic manipulative treatment (OMT) has been shown to improve cardiac indices, increase lymph flow rates through the thoracic duct, and decrease sympathetic tone in postoperative patients and those in intensive care. Therefore, we hypothesized that OMT may also increase sIgA levels in people under high levels of emotional and psychological stress, thereby enhancing immunity and potentially preventing subsequent infections."

"This study demonstrates the positive effect of OMT on sIgA levels in persons experiencing high stress. Results suggest that OMT may then have therapeutic preventive and protective effects on both healthy and hospitalized patients, especially those experiencing high levels of emotional or physiological stress and those at higher risk of acquiring upper respiratory tract infections."

Ruffini N, D'Alessandro G, Mariani N, Pollastrelli A, Cardinali L, Cerritelli F, 2015 **Variations of high frequency parameter of heart rate variability following osteopathic manipulative treatment in healthy subjects compared to control group and sham therapy: randomized controlled trial** Front Neurosci 9: 272 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4523739/>

"Methods: Sixty-six healthy subjects, both male and female, were included in the present 3-armed randomized placebo controlled within subject cross-over single blinded study. Participants were asymptomatic adults (26.7 ± 8.4 y, 51% male, BMI 18.5 ± 4.8), both smokers and non-smokers and not on medications. At enrollment subjects were randomized in three groups: A, B, C. Standardized structural evaluation followed by a patient need-based osteopathic treatment was performed in the first session of group A and in the second session of group B. Standardized evaluation followed by a protocolized sham treatment was provided in the second session of group A and in the first session of group B. No intervention was performed in the two sessions of group C, acting as a time-control. The trial was registered on clinicaltrials.gov identifier: NCT01908920.

Main Outcomes Measures: HRV was calculated from electrocardiography before, during and after the intervention, for a total amount time of 25 min and considering frequency domain as well as linear and non-linear methods as outcome measures.

Results: OMT engendered a statistically significant increase of parasympathetic activity, as shown by High Frequency power ($p < 0.001$), expressed in normalized and absolute unit, and possibly decrease of sympathetic activity, as revealed by Low Frequency power ($p < 0.01$); results also showed a reduction of Low Frequency/High Frequency ratio ($p < 0.001$) and Detrended fluctuation scaling exponent ($p < 0.05$).

Conclusions: Findings suggested that OMT can influence ANS activity increasing parasympathetic function and decreasing sympathetic activity, compared to sham therapy and control group."

"The OMT intervention consisted in a patient's need based treatment, thus no pre-determined protocol was applied. Osteopathic session lasted 25 min, 10 min for evaluation and 15 min for treatment. Techniques used in the present study were left at the discretion of the operator but limited to balance ligamentous techniques, balance membranous techniques and cranio-sacral techniques"

Molski P, Ossowski R, Hagner W, Molski S. 2009 **Patients with venous disease benefit from manual lymphatic drainage**. Int Angiol Apr;28(2):151-5. <http://www.ncbi.nlm.nih.gov/pubmed/19367246>

"After surgery, the MLD [manual lymphatic drainage] group had significantly better results than the control group in CEAP score ($P < 0.05$) and had comparable results for QoL [quality of life]. MLD improved ($P < 0.05$) VRI, CEAP score, anxiety and depression states. MLD [manual lymphatic drainage] can be an alternative or a supplementary procedure for patients surgically treated."

Ekici G, Bakar Y, Akbayrak T, Yuksel I. 2009 **Comparison of manual lymph drainage therapy and connective tissue massage in women with fibromyalgia: a randomized controlled trial**.

"The score for FIQ-2 (feel good) ($P = .036$) was higher, the score for FIQ-9 (anxiety) ($P = .019$) was lower in the MLDT group than in the CTM group"

"For this particular group of patients, both MLDT [manual lymphatic drainage technique] and CTM [connective tissue massage] appear to yield improvements in terms of pain, health status, and HRQoL [health-related quality of life]."

"However, MLDT was found to be more effective than CTM according to some subitems of FIQ (morning tiredness and anxiety) and FIQ total score. Manual lymph drainage therapy might be preferred"

Florance BM, Frin G, Dainese R, Nébot-Vivinus MH, Marine Barjoan E, Marjoux S, Laurens JP, Payrouse JL, Hébuterne X, Piche T 2012 **Osteopathy improves the severity of irritable bowel syndrome: a pilot randomized sham-controlled study.** Eur J Gastroenterol Hepatol Aug;24(8):944-9 <http://www.ncbi.nlm.nih.gov/pubmed/22546751>

"We prospectively assigned 30 patients with IBS (23F, 7M, mean age 45.8 ± 16.4 years) fulfilling the Rome III criteria in a 2/1 ratio to receive either osteopathy or sham osteopathy. Two separate sessions were performed at a 7-day interval (days 0 and 7) with a further 3 weeks of follow-up (day 28). The primary outcome included at least a 25% improvement in the IBS severity score at day 7. The secondary outcomes included the impact of IBS on quality of life, psychological factors, and bowel habits."

"The severity of IBS decreased in both groups at days 7 and 28. At day 7, this decrease was significantly more marked in patients receiving osteopathy compared with those receiving the sham procedure (-32.2 ± 29.1 vs. -9.0 ± 16.0 , mean difference normalized to the baseline $P=0.01$). This difference did not persist at day 28 ($P=0.4$). Both anxiety and depression scores decreased without difference between groups. Stool frequency and consistency were not significantly modified."

"Osteopathy improves the severity of IBS symptoms and its impact on quality of life."

Mehl-Madrone L, Kligler B, Silverman S, Lynton H, Merrell W 2007 **The impact of acupuncture and craniosacral therapy interventions on clinical outcomes in adults with asthma.** Explore (NY) Jan-Feb;3(1):28-36. <http://www.ncbi.nlm.nih.gov/pubmed/17234566>

"When treatment was compared with the control group, statistically treatment was significantly better than the control group in improving asthma quality of life, whereas reducing medication use with pulmonary function test results remained the same."

"Acupuncture and/or craniosacral therapy are potentially useful adjuncts to the conventional care of adults with asthma, but the combination of the two does not provide additional benefit over each therapy alone."

"Having a longer, more intensive treatment protocol with a single practitioner was associated with better reductions of anxiety on the BAI [Beck Anxiety Index]."

Dugaill P, Fassin S, Maroye L, Evers L, Klein P, Feipel V, 2014 **Effect of a general osteopathic treatment on body satisfaction, global self perception and anxiety: A randomized trial in asymptomatic female students** International Journal of Osteopathic Medicine Volume 17, Issue 2, June, Pages 94–101 <http://www.sciencedirect.com/science/article/pii/S1746068913001260>

"Thirty-four asymptomatic female volunteers completed baseline auto-questionnaires about anxiety, body satisfaction and global self-perception. Then, they were randomly assigned to OG or to control group (restful state)."

"At baseline, characteristics were comparable between groups. Following the intervention, we observed improvements in psychological state in both OG [general osteopathic treatment] and control groups. Nevertheless, OG had a significant larger effect over restful state for anxiety and global self-perception ($p < 0.02$)."

"The present study suggests that an osteopathic approach using articular and soft tissue mobilisations has an effect, at least in the short term, on anxiety and global body perception. Further investigation is needed to confirm the relevance and broaden the scope of the present study."

Poland RE, Gertsik L, Favreau JT, Smith SI, Mirocha JM, Rao U, Daar ES. 2013 **Open-label, randomized, parallel-group controlled clinical trial of massage for treatment of depression in HIV-infected subjects.** The Journal of Alternative and Complementary Medicine Apr;19(4):334-40 <http://www.ncbi.nlm.nih.gov/pubmed/23098696>

"The study objectives were to determine whether massage therapy reduces symptoms of depression in subjects with human immunodeficiency virus (HIV) disease."

"Study inclusion required being at least 16 years of age, HIV-seropositive, with a diagnosis of major depressive disorder. "

"Swedish massage and touch subjects visited the massage therapist for 1 hour twice per week. The touch group had a massage therapist place both hands on the subject with slight pressure, but no massage, in a uniform distribution in the same pattern used for the massage subjects."

"For both the ITT and completers analyses, massage significantly reduced the severity of depression beginning at week 4 ($p \leq 0.04$) and continuing at weeks 6 ($p \leq 0.03$) and 8 ($p \leq 0.005$) compared to no intervention and/or touch."

"The results indicate that massage therapy can reduce symptoms of depression in subjects with HIV disease. The durability of the response, optimal "dose" of massage, and mechanisms by which massage exerts its antidepressant effects remain to be determined."

Haller H, Lauche R, Cramer H, Rampp T, Saha FJ, Ostermann T, Dobos G 2016 **Craniosacral Therapy for the Treatment of Chronic Neck Pain: A Randomized Sham-controlled Trial** Clin J Pain May;32(5):441-9 <http://www.ncbi.nlm.nih.gov/m/pubmed/26340656/#ft>

"MATERIALS AND METHODS: A total of 54 blinded patients were randomized into either 8 weekly units of CST or light-touch sham treatment. Outcomes were assessed before and after treatment (week 8) and again 3 months later (week 20). The primary outcome was the pain intensity on a visual analog scale at week 8; secondary outcomes included pain on movement, pressure pain sensitivity, functional disability, health-related quality of life, well-being, anxiety, depression, stress perception, pain acceptance, body awareness, patients' global impression of improvement, and safety.

RESULTS: In comparison with sham, CST patients reported significant and clinically relevant effects on pain intensity at week 8 (-21 mm group difference; 95% confidence interval, -32.6 to -9.4; $P=0.001$; $d=1.02$) and at week 20 (-16.8 mm group difference; 95% confidence interval, -27.5 to -6.1; $P=0.003$; $d=0.88$). Minimal clinically important differences in pain intensity at week 20 were reported by 78% within the CST group, whereas 48% even had substantial clinical benefit. Significant between-group differences at week 20 were also found for pain on movement, functional disability, physical quality of life, anxiety and patients' global improvement. Pressure pain sensitivity and body awareness were significantly improved only at week 8. No serious adverse events were reported.

DISCUSSION: CST was both specifically effective and safe in reducing neck pain intensity and may improve functional disability and the quality of life up to 3 months after intervention."

Case controlled studies

Number of studies: 1

Reis MS, Durigan JL, Arena R, Rossi BR, Mendes RG, Borghi-Silva A 2014 **Effects of posteroanterior thoracic mobilization on heart rate variability and pain in women with fibromyalgia**. Rehabil Res Pract 2014:898763 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4060169/>

"Fibromyalgia (FM) has been associated with cardiac autonomic abnormalities and pain. Heart rate variability (HRV) is reduced in FM with autonomic tone dominated by sympathetic activity. The purpose of this study was to evaluate the effects of one session of a posteroanterior glide technique on both autonomic modulation and pain in woman with FM. This was a controlled trial with immediate followup; twenty premenopausal women were allocated into 2 groups: (i) women diagnosed with FM (n = 10) and (ii) healthy women (n = 10). Both groups received one session of Maitland mobilization grade III posteroanterior central pressure glide, at 2 Hz for 60 s at each vertebral segment. Autonomic modulation was assessed by HRV and pain by a numeric pain scale before and after the intervention. For HRV analyses, heart rate and RR intervals were recorded for 10 minutes. FM subjects demonstrated reduced HRV compared to controls. Although the mobilization technique did not significantly reduce pain, it was able to improve HRV quantified by an increase in rMSSD and SD1 indices, reflecting an improved autonomic profile through increased vagal activity. In conclusion, women with FM presented with impaired cardiac autonomic modulation. One session of Maitland spine mobilization was able to acutely improve HRV."

Other controlled clinical trials

Number of studies: 3

Korotkov K, Shelkov O, Shevtsov A, Mohov D, Paoletti S, Mirosnichenko D, Labkovskaya E, Robertson L 2012 **Stress reduction with osteopathy assessed with GDV electrophotonic imaging: effects of osteopathy treatment**. The Journal of Alternative and Complementary Medicine Mar;18(3):251-7 <http://www.ncbi.nlm.nih.gov/pubmed/22420738>

OBJECTIVES:

The purpose of this study is to explore how osteopathy treatments influence certain measurable aspects of the human biofield; namely, various calculated parameters of finger corona discharge patterns produced by high-voltage electrophotography.

METHODS:

The Gas Discharge Visualization camera was used to assess subjects before and after osteopathy treatment. Thirty-three (33) apparently healthy adults (20-56 years old) took part in the study. The patterns of light emitted from the subjects' fingertips were digitally recorded and computer analyzed. Parameters including normalized area, brightness, and right- and left-hand integrals were calculated and statistically compared.

RESULTS:

Most of the recipients of these osteopathic treatments experienced increase in fingertip fluorescence area and average intensity, reduction in stress levels, and improved blood pressure measurements. With all of these parameters simultaneously improving, the patients received a good benefit from these sessions.

CONCLUSIONS:

Virtually all subjects were in a good mood after treatment. Many of them had pain and muscle tension that disappeared. These changes were reflected in all parameters analyzed, in both psychosomatic and somatic states. Thus, osteopathic manipulations as administered in these two studies provide good, lasting relaxation. This study also provides the interesting observation that daily relaxation practices done by Dr. Paoletti enable him to work hard without additional stress.

Korotkov K, Shelkov O, Shevtsov A, Mohov D, Paoletti S, Mirosnichenko D, Labkovskaya E, Robertson L 2012 **Stress reduction with osteopathy assessed with GDV electrophotonic**

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Henley CE, Ivins D, Mills M, Wen FK, Benjamin BA. 2008 **Osteopathic manipulative treatment and its relationship to autonomic nervous system activity as demonstrated by heart rate variability: a repeated measures study.** Osteopathic medicine and primary care Jun 5;2:7 <http://www.ncbi.nlm.nih.gov/pubmed/18534024>

"The relationship between osteopathic manipulative treatment (OMT) and the autonomic nervous system has long been acknowledged, but is poorly understood. In an effort to define this relationship, cervical myofascial release was used as the OMT technique with heart rate variability (HRV) as a surrogate for autonomic activity. This study quantifies that relationship and demonstrates a cause and effect."

"Predominantly parasympathetic responses were observed with subjects in the horizontal position, while a 50-degree tilt provided a significantly different measure of maximum sympathetic tone ($p < 0.001$). Heart rate changed in all subjects with change in position; respirations remained constant. When OMT was performed in a sympathetic environment (tilt), a vagal response was produced that was strong enough to overcome the sympathetic tone. There was no HRV difference between sham and control in either the horizontal or tilt positions."

"The vagal response produced by the myofascial release procedure in the maximally stimulated sympathetic environment could only have come from the application of the OMT. This demonstrates the association between OMT and the autonomic nervous system. The lack of significance between control and sham in all positions indicates that HRV may be a useful method of developing sham controls in future studies of OMT."

Edwards DJ, Toult C, 2018 **An evaluation of osteopathic treatment on psychological outcomes with patients suffering from chronic pain: A prospective observational cohort study collected through a health and well-being academy** Health Psychology Open vol. 5, 1, First Published May 10. <http://journals.sagepub.com/doi/full/10.1177/2055102918774684>

"Co-morbid mental health conditions such as anxiety, depression and fear avoidance are often associated with chronic pain. This novel study aimed to explore the impact of osteopathic treatment on several psychological outcome measures relating to anxiety, depression, mental health and fear avoidance for a chronic pain population receiving osteopathic treatment over a 2-week period. The findings show that there were significant reductions in anxiety, pain, mental health dysfunction and improvements in self-care. These results are promising, and it is suggested that now a full-scale randomised controlled trial should be conducted."

Chiarotto A, Fortunato S, Falla D 2015 **Predictors of outcome following a short multimodal rehabilitation program for patients with whiplash associated disorders.** Eur J Phys Rehabil Med Apr;51(2):133-41 <http://www.ncbi.nlm.nih.gov/pubmed/24896143>

"Patients with whiplash associated disorders (WAD) may present with physical and psychological symptoms which persist long after the initial onset of pain. Several studies have shown that therapeutic exercise for motor and sensorimotor control combined with manual therapy in a multimodal rehabilitation (MMR) program is effective at improving pain and disability in patients with neck disorders. To date, no studies have investigated which self-reported physical or psychological symptoms are predictive of response to this MMR program." "After treatment, patients exhibited significant improvements in all evaluated outcomes (all $P < 0.01$). Regression models accounting for 35% and 36% of the variance in pain intensity outcomes included average pain intensity over the previous week and pain catastrophizing as significant predictors. Disability and pain catastrophizing were predictors of changes in disability following the MMR program explaining 49% of the variance in the model. Furthermore, higher PTSS at baseline was a significant predictor of PTSS after treatment, explaining 55% of the variance in the model. CONCLUSION: Improved outcomes on pain intensity, disability and PTSS following a MMR program could be partially predicted based on the patient's initial presentation."

D'Ippolito M, Tramontano M, Buzzi MG. 2017 **Effects of Osteopathic Manipulative Therapy on Pain and Mood Disorders in Patients With High-Frequency Migraine.** J Am Osteopath Assoc Jun 1;117(6):365-369 <https://www.ncbi.nlm.nih.gov/pubmed/28556858>

"CONTEXT: The substantial functional impairment associated with migraine has both physical and emotional ramifications. Mood disorders are often comorbid in patients with migraine and are known to adversely affect migraine activity. OBJECTIVES: To explore the effects of osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) on pain and mood disorders in patients with high-frequency migraine. METHODS: Retrospective review of the medical records of patients with high-frequency migraine who were treated with OMTh at the Headache Istituto di Ricovero e Cura a Carattere Scientifico Fondazione Santa Lucia from 2011 to 2015. Clinical assessments were made using the Headache Disability Inventory (HDI), the Headache Impact Test (HIT-6), the Hamilton Depression Rating Scale (HDRS), and the State-Trait Anxiety Inventory (STAI) forms X-1 and X-2. RESULTS: Medical records of 11 patients (6 women; mean age, 47.5 [7.8] years) with a diagnosis of high-frequency migraine who participated in an OMTh program met the inclusion criteria and were included in the study. When the questionnaire scores obtained at the first visit (T0) and after 4 OMTh sessions (T1) were compared, significant improvement in scores were observed on STAI X-2 (T0: 43.18 [2.47]; T1: 39.45 [2.52]; $P < .05$), HIT-6 (T0: 63 [2.20]; T1:

56.27 [2.24]; P<.05), and HDI (T0: 58.72 [6.75]; T1: 45.09 [7.01]; P<.05).

CONCLUSION: This preliminary study revealed that patients with high-frequency migraine and comorbid mood disorders showed significant improvement after four 45-minute OMTh sessions. Further investigation into the effects of OMTh on pain and mood disorders in patients with high-frequency migraine is needed."

Harrison RE, Page JS 2011 **Multipractitioner Upledger CranioSacral Therapy: descriptive outcome study 2007-2008**. The Journal of Alternative and Complementary Medicine Jan;17 (1):13-7 <http://www.ncbi.nlm.nih.gov/pubmed/21214395>

"Outcome by diagnostic groups suggested that UCST [Upledger craniosacral therapy] is particularly effective for patients with headaches and migraine, neck and back pain, anxiety and depression, and unsettled babies. Seventy percent (70%) of patients on medication decreased or discontinued it, and patients' average general practitioner consultation rate fell by 60% in the 6 months following treatment."

"Patients' ages ranged from neonates to 68 years. Seventy-four percent (74%) of patients reported a valuable improvement in their presenting problem. Sixty-seven percent (67%) also reported a valuable improvement in their general well-being and/or a second health problem. Outcome by diagnostic groups suggested that UCST is particularly effective for patients with headaches and migraine, neck and back pain, anxiety and depression, and unsettled babies."

Case reports

Number of studies: 1

Leach J 2008 **Osteopathic support for a survivor of gastric cancer: A case report** International Journal of Osteopathic Medicine Volume 11, Issue 3, September , Pages 106–111 <http://www.sciencedirect.com/science/article/pii/S174606890800031X>

"An older male patient received eight consultations over a period of 10 months, some three years after his cancer diagnosis and treatment. Osteopathic management included manual treatment to improve musculoskeletal mobility, cranial osteopathic treatment to release tension in the deeper fascia, discussion of dietary strategies and advice and education about the origin of his symptoms due to a total gastrectomy and cancer chemotherapy. After treatment his physical symptoms were reduced. His neck pain was reduced. Nausea and discomfort after eating disappeared. Frequency of diarrhoea, breathlessness and fatigue were improved. He gained weight and resumed social activities. "

"Osteopathic consultations provide time to engage in complex problems that may benefit from a holistic approach. The touch and body work involved in osteopathy can help the patient come to terms with altered body image and to talk openly about anxieties. The Hay approach to diet appeared to be valuable in improving the quality of life for this particular patient after his gastrectomy."

Mixed results (significant for some outcomes, not others)

Number of studies: 2

Papa L, Mandara A, Bottali M, Gulisano V, Orfei S. 2012 **A randomized control trial on the effectiveness of osteopathic manipulative treatment in reducing pain and improving the quality of life in elderly patients affected by osteoporosis.** Clin Cases Miner Bone Metab Sep;9(3):179-83 <http://www.ncbi.nlm.nih.gov/pubmed>

Introduction

In the elderly population, a decrease in bone mineral density (osteoporosis) is often associated with a decrease in quality of life and an increase in self reported body pain. This pain originates from the musculoskeletal system and can potentially affect different areas of the body.

Aim

The aim of this study was to investigate the effect of osteopathic manipulative treatment (OMT) on self reported pain and quality of life in an elderly population.

Design

Randomized placebo controlled trial.

Methods

Patients were recruited from the Geriatric Department, Bassini Hospital (Milan, Italy). Patients were randomly assigned to either 6 sessions of OMT (n = 37 patients) or an equivalent number of sham manipulative treatment (SMT) (n = 35 patients). The main outcome variables were QOL measured by QUALEFFO -41 and overall bodily pain measured using a visual analog scale (VAS). Data were analyzed using a two factor ANOVA (treatment × time) for repeated measurements with an α level set at $p \leq 0.05$.

Results

Main result of this study was that OMT compared to SMT showed a significant decreased of disability. This effect was demonstrated by a significant interaction in the overall disability score ($p = 0.001$) and the Mental wellbeing ($p = 0.058$), Health perception ($p = 0.005$) and Pain ($p = 0.003$) QUALEFFO -41 subscales, while no significant difference (no interaction) for pain as measured by VAS and for the Daily activities, Walking, Household cleaning and Leisure time activities QUALEFFO -41 subscales ($p > 0.05$) was found. No adverse effects were recorded during the study.

Discussion

This study demonstrated that, in a group of elderly subjects affected by osteoporosis OMT was able to increase self reported QOL while the effect on body pain perception is unclear. This overall improvement in QOL appears to be caused by an improvement in psychological factors (i.e Mental wellbeing and Health perception) rather than physical factors. In fact, all QUALEFFO -41 subscales related to physical function demonstrated no significant interaction. The effect of OMT on Pain perception is less clear. In fact, there was no effect on pain as assessed by VAS while a significant improvement was observed when the QUALEFFO -41 subscale was used. This could be due to the metric properties of the two pain measurement methods; an alternative explanation could be that VAS measures mainly pain quantity while QUA-LEFFO -41 subscales measures mainly pain quality. The lack of effect of OMT on physical function needs to be confirmed by more direct measurements of this variable."

Plotkin BJ, Rodos JJ, Kappler R, Schrage M, Freydl K, Hasegawa S, Hennegan E, Hilchie-Schmidt C, Hines D, Iwata J, Mok C, Raffaelli D. 2001 **Adjunctive osteopathic manipulative treatment in women with depression: a pilot study.** J Am Osteopath Assoc Sep;101(9):517-23 <http://www.ncbi.nlm.nih.gov/pubmed/11575038>

"The authors assessed the impact of osteopathic manipulative treatment (OMT) as an adjunct to standard psychiatric treatment of women with depression. Premenopausal women with newly diagnosed depression were randomly assigned to either control (osteopathic structural examination only; n = 9) or treatment group (OMT; n = 8). Both groups received conventional therapy consisting of the antidepressant paroxetine (Paxil) hydrochloride plus weekly psychotherapy for 8 weeks. Attending psychiatrists and psychologists were blinded to group assignments. No significant differences existed between groups for age or severity of disease. After 8 weeks, 100% of the OMT treatment group and 33% of the control group tested normal

by psychometric evaluation. No significant differences or trends were observed between groups in levels of cytokine production (IL-1, IL-10, IL-2, IL-4, and IL-6) or in levels of anti-HSV-1, anti-HSV-2, and anti-EBV antibody. There was no pattern to the osteopathic manipulative structural dysfunctions recorded. The findings of this pilot study indicate that OMT may be a useful adjunctive treatment for alleviating depression in women."

"This study was a prospective, experimental, blinded, controlled study to examine the efficacy of OMT as an adjunctive therapy in the treatment of depression in women. The Institutional Review Board of Midwestern University approved the study protocol. Once informed consent was obtained, patients were randomly assigned to control or treatment groups."

"Data entry and analysis was also carried out in a blinded fashion."

"After interpretations of both psychiatric and immunologic data were recorded, the data from the records were entered by computer into a statistical file for analysis. The veracity of the use of OMT in treatment of depression was determined from the statistical findings only."

"Parametric tests to determine statistical significance between control and treatment groups were performed using one-way analysis of variance followed by Tukey-Kramer post-hoc analysis."